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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,635	01/29/2002	Shifeng Bill Wei	ORT-1585	7718
27777	7590	11/20/2003	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			OH, SIMON J	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/059,635	<b>Applicant(s)</b> WEI ET AL.	
	<b>Examiner</b> Simon J. Oh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicants' petition for extension of time and request for continued examination, both received on 16 October 2003.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 22 and 28-30 under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn with the previous amendment to the claims.

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 20, 31, 32, and 34-36 under 35 U.S.C. 102(b) as being anticipated by Hogan *et al.* is hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 22-36 under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.* are hereby withdrawn.

Claims 20-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan *et al.* (U.S. Patent No. 6,406,738 B1) in view of Wright *et al.* (U.S. Patent No. 5,595,759)

The previously cited Hogan *et al.* reference, WIPO Document No. 96/35413, will hereinafter be designated Hogan I. The Hogan *et al.* reference cited in this present rejection will be designated Hogan II.

The Hogan II document teaches a substrate coating for the electrostatic deposition of active substances (See Abstract). This material, in its powder form, has a particle size of less than 50 microns (See Column 4, Lines 45-54); and in one preferred embodiment, the powdered material has a mean particle size of about 10 microns, and substantially no particles larger than 100 microns in diameter (See Column 5, Lines 27-37). Polyethylene glycol with molecular weights of 20,000 and 6,000 are used in the coating material (See Examples 1 and 6). The process may employ various electrostatic effects, including triboelectric charging (See Column 6, Lines 20-25). Furthermore, the Hogan II document discloses that it is preferable that nearly all of the charged particles bear the same sign of charge (See Column 7, Lines 5-19). Various types of active agents may be included in the powder coating material, including oral contraceptive agents (See Column 10, Line 32). Preferably, the coating material comprises at least 0.5% by weight of the active agent based on the weight of the powder coating material. An example is cited where a 10 mg coating on a tablet may contain approximately at least 0.05 mg of the active ingredient (See Column 10, Lines 49-53).

The Hogan II reference does not explicitly mention norgestimate or ethinyl estradiol as suitable active agents for use in the disclosed powder coating. However, it would be obvious to one of ordinary skill in the art that the term “oral contraceptive agents” encompasses norgestimate or ethinyl estradiol, and that one of ordinary skill would know appropriate dosage amounts for these drugs. The Wright *et al.* reference is relied upon here as a teaching reference to show that norgestimate and ethinyl estradiol are known in the art as contraceptive agents, and that their particular combination is also known in the art (See Wright *et al.*, Column 2, Line 33). Claim limitations drawn to the particular molecular weight of polyethylene glycol to be used are not considered to be critical in view of the disclosure of the Examples in Hogan II. Claim limitations drawn to either the ratio of medicament to polyethylene glycol or to the particle size of the active agent are considered obvious over the broad disclosure of Hogan II (See Columns 5, 10, and 11).

Thus, the instantly claimed invention is *prima facie* obvious.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj0

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600